

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
Before the Board of Patent Appeals and Interferences

In re Patent Application of

SOUDA et al

Serial No. 08/354,726

Filed: 6 December 1994

For: PYRIDINE DERIVATIVES HAVING  
ANTI-ULCERATIVE ACTIVITY



Atty. Ref.: 423-27

Group: 1203

Examiner: Fan

#20  
4-18-98  
HP

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April 3, 1998

Honorable Commissioner of Patents  
and Trademarks  
Washington, DC 20231

APPEAL BRIEF

Sir:

Applicant hereby appeals the Final Rejection of October 7, 1997, Paper No. 17.

REAL PARTY IN INTEREST

The real party in interest is Eisai Co., Ltd., a corporation of Japan.

RELATED APPEALS AND INTERFERENCES

The appellant, the undersigned, and the assignee are not aware of any related  
appeals or interferences which will directly affect or be directly affected by or have a

04/07/1998 NCAERO 00000030 08354726  
01 FC:120 bearing on the Board's decision in this appeal.

**STATUS OF CLAIMS**

Claims 18 and 19 are pending and have been finally rejected.

**STATUS OF AMENDMENTS**

An amendment was filed April 2, 1998 and has not been considered as of the present date.

**SUMMARY OF INVENTION**

The claims are directed to a single chemical compound containing a methyl thio group (claim 18) or its sodium salt (claim 19). These compounds are useful as chemical intermediates to prepare highly active compounds for treating or preventing peptic ulcers. The compound is useful as an intermediate to produce pharmacologically active sulfinyl compounds and in fact it is this final compound that is the subject of claims of U.S. 5,045,552 which issued from this series of applications. It is known as rabeprazol sodium. Rabeprazol sodium possesses useful antibiotic properties and this is the subject of the evidence of record in this application.

### ISSUES

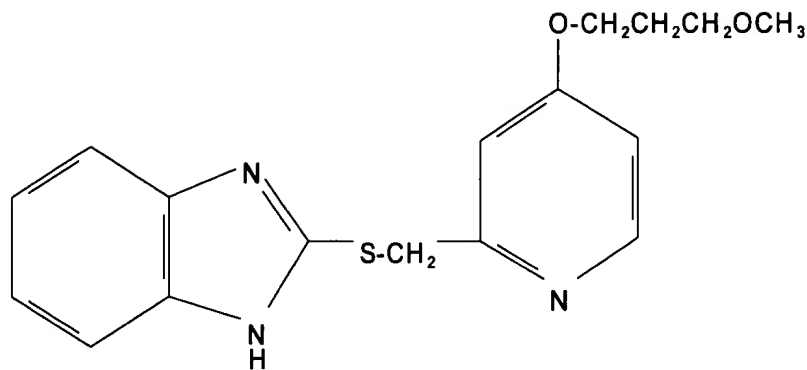
1. Is the combination of EP 074,341 in view of EP 198,208, when considered in light of the evidence of record, suggestive of the subject matter of claims 18 and 19?
2. Do claims 18 and 19 conflict with the first patent issued in this series, U.S. Patent No. 5,045,552, in terms of obviousness-type double patenting when the '552 patent is considered in view of GB 2,134,523?
3. Assuming that the first issue is resolved in favor of applicants, and the issue of obviousness-type double patenting is not, applicants intend to provide a terminal disclaimer to resolve this second issue.
4. The final rejection includes two provisional double-patenting rejections. A terminal disclaimer has been filed recently addressing these two provisional rejections.

### GROUPING OF CLAIMS

The claims may be grouped together for purposes of this appeal.

ARGUMENT

The appealed claims are directed to compounds having the structure



Claimed Compound

It is this compound that is converted to the corresponding sulfinyl compound that is the subject of an earlier application in this series, now U.S. Patent No. 5,045,552. The only difference in structure is that the claimed compound is thio whereas the patented compounds are sulfinyls. Indeed, it is the structure of the presently claimed compound that affords the desired sulfinyl compounds and is, in fact, the last step in the synthesis process for making such compounds. There is only one structural change in the compound made prior to the finished product. Thus, it is clear that the claimed compound serves as valuable and useful intermediates to produce the patented compounds. From the record of great grandparent application and the present application as well it is clear that the patented compounds have unexpected properties compared to related compounds in the prior art. These unexpected properties in part flow from the

specific structure of the compounds of the present application and, in particular, the substituent on the four position of the pyridine ring which remains unchanged between the claimed compounds of the present application and the patented compounds.

Attention is directed to *In re Magerlein*, 202 U.S.P.Q. 473 at 478 (CCPA 1979)

where the court stated:

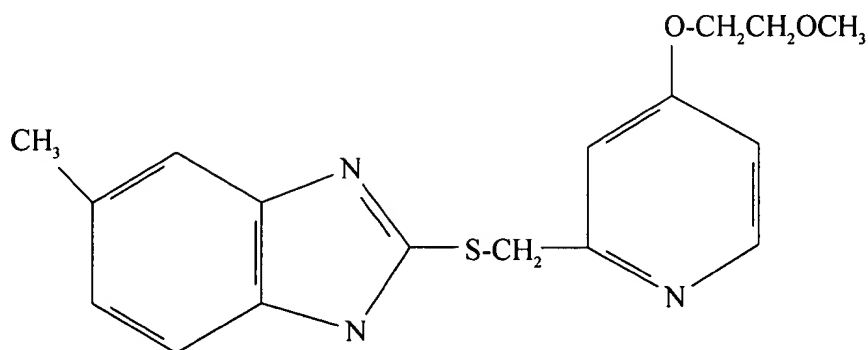
"...evidence of an unexpectedly superior activity or property of an end product may, under appropriate circumstances, be considered in the determination of the nonobviousness of the claimed intermediate."

And thereafter concluded

"...we are persuaded that the capacity of an intermediate to contribute to an end product that feature which causes the end product to possess an activity or property that is unexpectedly superior to that of a prior art end product is a 'property' that inures to the benefit of the intermediate and that can be considered as part of the 'subject matter as a whole' in determining the nonobviousness of the intermediate."

Based on the above legal reasoning which is controlling in this case, it is respectfully submitted that the claims of the present application defined inventive subject matter -- the compounds of the present application include features which cause the end product to possess an activity or property that is unexpectedly superior to that of the prior art end products. This has been demonstrated by the issuance of U.S. Patent No. 5,045,552 and as explained above.

A compound of EP '314 considered by the examiner as representative of that disclosure is as follows:



EP 074,341 Hassle

In addition to a methyl group in the five position of the benzimidazol ring, the substituent at the four position of the pyridine ring is methoxyethoxy, an issue directly pertinent to and dealt with during the examination of the application that matured in the U.S. Patent No. 5,045,552.

The art-based rejection of claims 18 and 19 argues that the *Magerlein* decision is not controlling because the intermediate compound claimed in the present application "has other uses (treating gastric disorders) besides to be used to make the final product." The point here is that the intended use of this intermediate compound is to make the final product which is an active, commercially significant material. The fact that when later tested these intermediate compounds have antibiotic activity on their own was surprising an unexpected. However, the fact that they possess such activity on their own is irrelevant when considered in respect of the doctrine of *Magerlein*.

The Official Action also complains that the unexpected advantage, that is antibiotic activity, "is not disclosed in the original specification." Indeed, it need not be for, as established in the amendment filed to the final rejection on April 2, 1998, one of ordinary skill in the art would be aware of this activity by virtue of at least two publications available as of the priority date of the present application. There is no requirement that a patent applicant disclose that which is already well known in the art, thus this reason for dismissing fair consideration of the evidence is inappropriate.

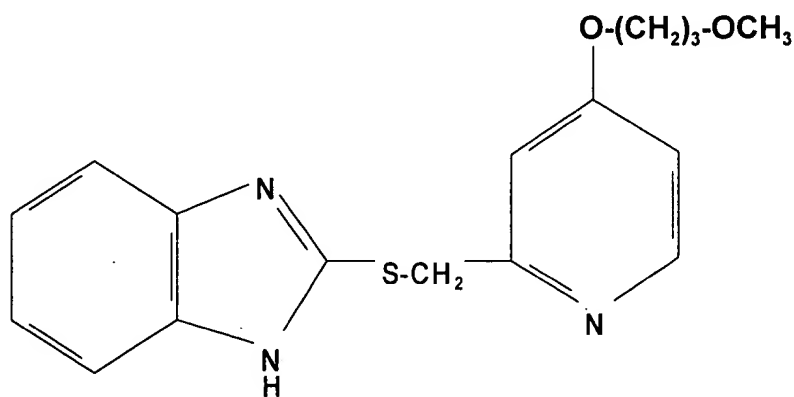
Applicants also dispute the assertion that the closest compound has now been compared to the claims of the present application. Applicants have already addressed this material and successfully overcome it for the reasons explained above.

Also included in the final rejection is an obviousness-type double-patenting rejection over the claims of U.S. Patent No. 5,045,552, a patent issuing an earlier application in this series. The rejection is not well taken because the combination of documents is not suggestive of the claimed subject matter. To substitute one group for the other is mere hindsight reconstruction of what was known in the art at the time of the present invention. There is no indication that such a change would provide useful starting materials of the type defined by the appealed claims.

In addition to the above, counsel wishes to defer consideration of the double-patenting rejection until such time as the art rejection is overcome. Thus, when the art rejection is reversed, applicants consider filing a terminal disclaimer to resolve the obviousness-type double-patenting rejection in the event the Board affirms that rejection.

**CLAIMS ON APPEAL**

18. A compound represented by the formula:



or a pharmaceutically acceptable salt thereof.

19. The compound of claim 18 as the sodium salt.



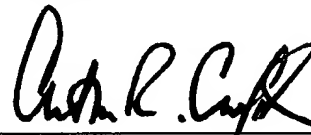
**CONCLUSION**

In conclusion it is believed that the application is in clear condition for allowance; therefore, early reversal of the Final Rejection and passage of the subject application to issue are earnestly solicited.

Respectfully submitted,

**NIXON & VANDERHYE P.C.**

By: \_\_\_\_\_



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